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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,691	05/08/2005	Jill Van Winkle	AG03-005C-US	3095

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EXAMINER

KUMAR, VINOD

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/509,691	Applicant(s) VAN WINKLE ET AL.	
	Examiner Vinod Kumar	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/16/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 6 is rejected under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter. The claim reads on a wild type seed from a transgenic plant. Given meiotic segregation during the formation of male and female gametes, and genetic reassortment and recombination following pollination leading to seed production, the claim broadly reads on untransformed seed which is a product of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-3, the metes and bounds of "ortholog" are unclear as it is not defined.

Claim 3, it is unclear how progenitor cells differ from other plant cells.

In claim 3b "increased" is a relative term lacking a comparative basis.

In claim 4 "over-expressed" is a relative term lacking a comparative basis.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 2, does not reasonably provide enablement for ortholog(s) of DRO2. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are broadly drawn to a transgenic plant or a method of producing said transgenic plant with increased drought tolerance comprising transforming plant cells with a vector comprising a nucleotide sequence that encodes a DRO2 polypeptide comprising the amino acid sequence as defined in SEQ ID NO: 2 or an ortholog thereof,

and wherein the transformed cells comprising said vector are grown to produce said transgenic plant.

The specification teaches generation of transgenic plant with increased drought tolerance by transformation of plant cells with an activation tagging construct and subsequently regenerating transgenic plant. See Example 1 on pages 17-18. The specification also describes characterization of the T-DNA insertion in transgenic plants exhibiting the altered drought tolerance phenotype. See Example 2 on page 18 and first paragraph on page 19.

Claims 1, 3 and the claims dependent therefrom encompass any ortholog of SEQ ID NO: 2 that produce drought tolerance phenotype in transgenic plant cell or plant regenerating from said cell. Specification does not teach working examples of orthologs of SEQ ID NO: 2 producing drought tolerant phenotype in transgenic plant. No guidance is provided as to how said orthologs can be determined without undue experimentation. The specification does not provide guidance as to how inoperable embodiments can be reliably eliminated without undue experimentation

The polypeptide defined in SEQ ID NO: 2 is a plant transcription factor belonging to Dof family of plant transcription factors. OBP1 that has 100% sequence identity with DRO2 polypeptide of instant contains a highly conserved Dof domain, a zinc finger DNA-binding domain and is constitutively expressed both in plants to mediate variety of plant-specific signals including drought. See paragraphs 1-3 on page 3 of specification. Dof proteins may share highly conserved Dof domain that has DNA binding activity for transcription activation, divergent physiological roles of Dof proteins have been suggested. See Yanagisawa (Trends in Plant Science, 7:555-560, 2002) which clearly shows that Dof proteins may be involved in light, hormone or defense responses (see

Art Unit: 1638

Table 1 on page 556. It is well established in the art that proteins with zinc finger DNA-binding domains also respond to variety of environmental stresses.

Since claims 1 and 3 encompass any nucleotide sequence encoding a polypeptide having amino acid sequence that is not 100% identical to SEQ ID NO: 2 but may be designated as an ortholog due to presence of conserved Dof domain, does not necessarily imply that over-expression of such an ortholog in transgenic plant cell or plant would actually produce drought tolerant phenotype. Keeping in view the divergent roles of plant Dof proteins and lack of any guidance in the specification about over-expression of any DRO2 ortholog in transgenic plant cell or plant, it will be highly unpredictable to guess whether over-expression of said ortholog(s) of DRO2 will actually be able to produce drought tolerant phenotype in the transgenic plant tissue. Undue experimentation would be required by a skilled artisan to produce transgenic plant with increased drought tolerance comprising over-expression of nucleotide sequence encoding a polypeptide that is not 100% identical to SEQ ID NO: 2, except for differences due to genetic code degeneracy. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a transgenic plant or a method of producing said transgenic plant with increased drought tolerance comprising transforming plant cells with a vector comprising a nucleotide sequence that encodes a DRO2 polypeptide comprising the amino acid sequence as defined in SEQ ID NO: 2 or an ortholog thereof, and wherein the transformed cells comprising said vector are grown to produce said transgenic plant.

The specification describes generation of transgenic plant with increased drought tolerance by transformation of plant cells with an activation tagging construct and subsequently regenerating transgenic plant. See Example 1 on pages 17-18. The specification also describes characterization of the T-DNA insertion in transgenic plants exhibiting the altered drought tolerance phenotype. See Example 2 on page 18 and first paragraph on page 19.

The claims reciting orthologs lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass DRO2 protein from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single SEQ ID NO: 2 isolated from *Arabidopsis*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in art to predictably determine such mutants and allelic variants of other plants, or the structure of DRO2 proteins from other plants and organisms, absent

Art Unit: 1638

further guidance. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111. Thus it is quite clear that the invention encompassed in claims 1, 3 and claims dependent therefrom was never reduced to practice as Applicants fail to disclose said structures and correlate them with the function of drought tolerance.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Alvim et al. (Plant Physiol., 126:1042-1054, Published July 2001)

Claims are broadly drawn to a transgenic plant or a method of producing said transgenic plant with increased drought tolerance comprising transforming plant cells with a vector comprising a nucleotide sequence that encodes a DRO2 polypeptide comprising the amino acid sequence as defined in SEQ ID NO: 2 or an ortholog thereof,

and wherein the transformed cells comprising said vector are grown to produce said transgenic plant.

Alvim et al. teach transgenic plant of tobacco and a method of producing said transgenic plant comprising over-expressing BiP in transgenic plant with drought tolerance phenotype. See Figure 5 on page 1047, Figure 6 on page 1048 and page 1051 of materials and methods. This rejection is made because specification does not teach structure and function of orthologs, and thus orthologs in claims 1-3 read on any protein capable of producing drought tolerance phenotype when transformed into a plant cell to produce a transgenic plant.

Conclusion

No claims are allowed. SEQ ID NO: 2 is free from prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vinod Kumar, Ph.D.
November 18, 2005.


PHUONG T. BUI
PRIMARY EXAMINER
11/18/05